The CPHS Executive Committee initiated a Human Research Protection Program (HRPP) quality improvement program in 2010 to identify strategies to reduce regulatory burdens for researchers as well as for CPHS members and CPHS staff, while also providing the highest quality of protection for human subjects participating in research. As part of our effort to improve the transparency of CPHS activities, I’m pleased to present the sixth annual CPHS Faculty Report. This document provides metrics describing CPHS activities in 2015, including workload and time to approval data.

Despite the increase in new applications (from 678 in 2009 to 1,051 in 2015), there has been a steady decrease over the years in the time to approval (Fig 1), which is the time from initial submission of the protocol to final approval. This includes the time taken by the CPHS staff to process applications and for CPHS members to review the submissions, as well as the time taken by investigators to respond to deficiencies, queries, and stipulations.

As shown in Fig 1, the median time to approval for initial submissions reviewed at a full board meeting was reduced from 106 days in 2009 to 69 days in 2014 and further reduced to 62 days in 2015. Expedited reviews were reduced from a median of 46 days in 2009 to 29 days in 2014 and remained steady at 29 days in 2015. The time to approval for exempt applications increased from 8 days in 2014 to 13 days in 2015, but was nonetheless lower than the median time to approval in the years 2009 through 2012.

CPHS has implemented various strategies to reduce regulatory burdens. For instance, CPHS staff make a concerted effort to assign the most suitable level of review based on the research risks. Over 80% of the protocols approved in 2015 were exempt or reviewed by an expedited procedure.

CPHS has also worked to reduce the number of times an application is returned to study teams for corrections, a factor that increases time to approval. Applications are returned most often due to missing documents, such as CVs and human subjects training. To address this issue, CPHS staff worked with study teams to attach CVs to the user profile so that the CV can be used for multiple protocols. Also, instead of requiring investigators and research staff to provide the CITI training certificate, IRB staff began recording human
subjects training directly from the CITI website. These actions have reduced the number of times a protocol is returned back for corrections. Indeed, the number of submissions of corrections was reduced from 2,706 in 2014 to 1,923 in 2015, despite there being more total submissions in 2015 (8,692) than in 2014 (8,415).

The CPHS Executive Committee continues to monitor the CPHS review process to improve the quality and efficiency of UTHealth’s human research protection program. To read the entire report visit CPHS Faculty Report. Please send your comments, concerns, and feedback to clinicaltrials@uth.tmc.edu.

“ClinicalTrials.gov Records Need Attention”

Many of you received an email on May 10, 2016 from ClinicalTrials.gov with the subject line “ClinicalTrials.gov Records Need Attention,” which asked you to update your records and/or resolve any issues. If so, please remember to address any problems with your record(s).

If you need help with any aspect of the process, please contact Elizabeth Gendel at Elizabeth.M.Gendel@uth.tmc.edu or 713-500-3587.

Upcoming Certification Testing Dates

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on August 6, 2016 with a registration deadline of June 25, 2016. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in September and October of 2016. Applications are due by August 15, 2016, and you can find more information here.
Source Documentation

Researchers must create and maintain source documents in compliance with Good Clinical Practice (GCP) guidelines.

The purpose of source documents is to document the existence of the research subject and substantiate the integrity of the research data collected. Source documents should include original documents related to the research, to medical treatment, and to the history of the subject.

Source data includes medical history information, medical examination results, lab results, demographic data, subject ID, drug or device dispensing information, informed consent, IRB approval, visit dates, concomitant medication, and intercurrent illnesses.

Some examples of source documents are:
- hospital records
- clinical and office charts
- laboratory notes
- subjects' diaries or evaluation checklists
- pharmacy dispensing records
- recorded data from automated instruments
- copies or transcriptions certified after verification as being accurate copies
- photographic negatives
- microfilm or magnetic media
- x-rays
- subject files
- records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the research

In 2015, inadequate and inaccurate records represented the second most common finding in FDA’s GCP inspections of clinical investigators performing drug trials.

The FDA has set forth requirements for recordkeeping and record retention in clinical research (21 CFR 312.57, 312.62, and 812.140). However, the format and content of source data and source documents are not explicitly described in the Federal regulations, and the FDA has adopted the International Committee on Harmonization’s (ICH’s) guidance for good clinical practice (ICH-GCP). Additional FDA guidance on source documents can be found at this link under Recordkeeping and Record Retention.

UTHHealth’s Clinical Trials Resource Center (CTRC) provides a guidance document on source documentation at this link, which is posted on CTRC’s webpage on GCP at this link.

If you have questions, please contact the CTRC at clinicaltrials@uth.tmc.edu. You are also welcome to set up a not-for-cause monitoring visit with CTRC.
Upcoming Training

Clinical Research Finance Lunch and Learn
Objective: Provide staff members guidance on research financial topics (e.g., budgeting, billing, and coverage analysis). Also, a forum to introduce or update financial matters and to present questions or concerns for discussion in an open setting with peers.
Date: June 8, 2016
Time: 11:30 am – 12:30 pm
Location: MSB 2.135
Feel free to bring your lunch.
Registration is not required

More information here.

Date: June 28, 2016 (Research Career Development, Karen Motsinger)
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided for the first 40 participants.
Registration is not required.

Orientation for Clinical Research Staff
Objective: Educate new clinical research personnel on clinical trial management, as well as IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.
Date: June 28, 2016
Time: 9:00 am – 11:30 pm
Location: MSB G.100
Registration is required. Register here.

Clinical Research Budgeting and Billing Training
Objective: A hands-on workshop that will cover the processes for billing, coverage analysis, building a research budget, and reconciliation.
Date: June 28, 2016
Time: 1:00 pm – 4:00 pm
Location: MSB B.500
Registration is required. Register here.

iRIS Training
Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth’s CPHS and AWC.
Date: June 9, 2016
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (Parking will be validated)
Registration is required. Register here.

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.
Date: June 28, 2016
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided for the first 40 participants.
Registration is not required.

About the Clinical Trials Resource Center
It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit https://www.uth.edu/ctrc/ for more information.

Sujatha Sridhar, MBBS, MCE
Director
713-500-3622

Catrina VanAllen, MBA, CCRP
Senior Research Compliance Specialist
713-500-3578

Elizabeth Massey Gendel, PhD
Senior Research Compliance Specialist
713-500-3587

Rosemary Tran, BS
Graduate Assistant
713-500-3551